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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/828,838 | 04/20/2004 | Stephanie M. Kladakis | 022956-0261 | 5281 |

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| EXAMINER |
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WOODWARD, CHERIE MICHELLE

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| ART UNIT | PAPER NUMBER |
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1647

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| NOTIFICATION DATE | DELIVERY MODE |
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09/02/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

| | | | |
|------------------------------|---------------------------------------|----------------------------------------|--|
| Office Action Summary | Application No. 10/828,838 | Applicant(s) KLADAKIS ET AL. | |
| | Examiner CHERIE M. WOODWARD | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27, 32, and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/24/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 8/24/2010 has been entered.

Formal Matters

2. Claims 9, 15, 22, 28-31, and 34 have been cancelled by Applicant. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 are pending and under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 8/24/2010 has been considered by the examiner to the extent possible. Foreign language documents have been considered only insofar as their abstracts are in English. A signed copy is attached hereto. It is noted that Applicant has not provided any statement of relevancy, materiality, or any indication of the application of the references to the claims. Additionally, there is no statement as to materiality or relevancy as to any of the references cited in the listing of copending cases in the transmittal letter, which has also been considered and a signed copy is attached hereto. Applicant has made no attempt to relate the submitted documents to the issues raised and discussed in the file wrapper prosecution history. Applicant is reminded of the requirements of 37 CFR 1.56 and *Li Second Family Limited Partnership v. Toshiba Corp.*, 56 USPQ2d 1681 (Fed. Cir. 2000); accord *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.* 487 F.3d 897, 913. (Fed.Cir.2007). The cited references and copending applications have been considered to the extent possible given these shortcomings.

Non-Statutory Obviousness-Type Double Patenting Rejections

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the

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conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-8, 10-14, 16-21, 23-27, 32, and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36 and 37 of copending Application No. 11/427,477 (notice of allowance mailed 6/8/2010, but an issue fee has not been paid to date). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to overlapping subject matter. The instant application is a parent application to the CIP '477 application. The instant claims overlap significantly with the claims 36 and 37 (product by process claims drawn to a repair device) in the '477 application. Structure and functional limitations recited in the instant claims, but not specifically recited in the claims of the '477 application may be found in the specification of the '477 application. The instantly claimed subject matter is taught in claims 36-37 in the '477 CIP application and, as dependent claims, they encompass the structural and functional repair device limitations of independent claim 32 and dependent claims 33-35. The GDF-5 and rhGDF-5 of claims 36 and 37 of the '477 CIP is taught in the instant specification at paragraph 71.

Applicant was advised in the '477 CIP Requirement for Restriction/Election mailed 4/10/2008 (pages 2-3) that the product device claim and the method of surgically repairing meniscal defects were linked by the product of claim 1. However, when the product and method were regarded as allowable, they were rejoined to the extent that the product was allowed as a product-by-process claim in claims 36 and 37. However, Applicant cancelled claims 1-32 (which included withdrawn claims 1-20 drawn to the

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product claims) of the '477 CIP in the claim set of 5/10/2010. In the instant case, a Requirement for Restriction/Election was also made on the basis of restriction between the product and process claims (see Office Action of 1/8/2007). The method claims were cancelled by Application in the instant application in the claim set filed 5/10/2010. The instant case was indicated for allowance on 5/21/2010 and proceeded without a requirement for a terminal disclaimer on the basis that it was an earlier filed case. However, upon further consideration and in light of both the indicated allowance in the '477 CIP application and the RCE in the instant case, a terminal disclaimer is required in the instant case over the '477 CIP. Applicant is reminded that 35 USC 121 is not applicable in the instant situation because the '477 application is a CIP. Applicant is also reminded that MPEP § 804 (II) states, "When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure." (Emphasis added). "Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970)."

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the phrase "greater than about" and "less than about." The metes and bounds of these claims are unclear and confusing. Applicant is encouraged to review claims 19-21 for acceptable claim language. Applicant is also referred to *Ex parte Miyazaki* (BPAI 11/19/2008) (Horner, APJ) (precedential). A five member expanded panel of the Board held that "if a claim is amenable to two or more plausible claim constructions, the USPTO is justified in requiring applicant to more precisely define the metes and bounds of the claimed invention by holding the claim unpatentable under 35 USC 112, second paragraph, as indefinite." *Mizayzaki*, slip op. at 11-12.

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Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647